

UNITED STATES DISTRICT COURT

DISTRICT OF MINNESOTA

Crim. No. : 10-\_\_\_\_ (\_\_\_\_)

10-mj-67 (DWF)

UNITED STATES OF AMERICA,

Plaintiff,

v.

GUIDANT LLC,  
formerly d/b/a  
GUIDANT CORPORATION,

Defendant.

PLEA AGREEMENT AND  
SENTENCING STIPULATIONS

The United States of America and Guidant LLC ("Defendant" or "Guidant"), an Indiana limited liability company, formerly doing business as Guidant Corporation, an Indiana corporation, and which is a wholly-owned subsidiary of Boston Scientific Corporation, hereby enter into the following Plea Agreement pursuant to Rule 11(c)(1)(C) of the Federal Rules of Criminal Procedure and agree to resolve this case on the following terms and conditions. Any reference to the United States or the Government in this agreement shall mean the Office of the United States Attorney for the District of Minnesota and the Office of Consumer Litigation of the Civil Division of the United States Department of Justice.

FACTS

The Government and Guidant agree to the following facts:

Background

For purposes of this Plea Agreement, the "relevant period" is April 16, 2002 through June 17, 2005. All relevant conduct during the relevant period was undertaken by Guidant before it was acquired by Boston Scientific on April 22, 2006. During the relevant period, Guidant was a corporation organized and existing under the laws of the State of Indiana doing business as Guidant Corporation with its principal place of business in Indianapolis, Indiana. During the relevant period, Guidant, through the operation of several subsidiaries and affiliated entities, including Cardiac Pacemakers, Inc. and Guidant Sales Corporation, engaged in the development, manufacture, processing, packaging, sale, marketing, and interstate distribution of medical devices including:

- The Ventak Prizm 2 DR, Model 1861, implantable cardioverter-defibrillator ("ICD")
- The Contak Renewal 1, Model H135, cardiac resynchronization therapy-defibrillator ("CRT-D"); and
- The Contak Renewal 2, Model H155, cardiac resynchronization therapy-defibrillator.

These devices were Class III medical devices within the meaning of 21 U.S.C. § 321 and 21 U.S.C. § 360c and must be approved by FDA prior to their being marketed in the United

States. The Ventak Prizm 2 DR was approved by FDA on or about August 4, 2000. The Contak Renewal 1 was approved by FDA on or about December 20, 2002.

Facts Supporting Count One

The FDCA and its implementing regulations required manufacturers of Class III medical devices to submit various reports and notifications to the FDA. Guidant was required, pursuant to 21 C.F.R. § 814.84(b) and the conditions of approval for these devices to annually submit to FDA a post-approval report identifying any changes it made to the Prizm 2 and Renewal 1.

On or about November 13, 2002, Guidant implemented a change to the Ventak Prizm 2 DR which involved the application of additional insulation and which corrected a device flaw that had resulted in several devices short-circuiting when attempting to deliver therapy. Such short circuiting, also known as "arcing," could render the device unable to provide life-saving therapy when needed.

On or about August 19, 2003, Guidant submitted its periodic post-approval report on the Ventak Prizm 2 DR to FDA as required by 21 C.F.R. § 814.84(b) and the conditions of approval of the device's PMA. In that required report to FDA, Guidant described the November 13, 2002, change to the Ventak Prizm 2 DR as one which:

- Did not affect the safety and efficacy of the device; and
- Did not affect device performance.

These statements by Guidant were materially false and misleading because the engineering change Guidant executed did, in fact, affect the safety, efficacy, and performance of the Ventak Prizm 2 DR. In fact, there have been no reports that any devices manufactured after that change experienced such an arcing failure. Guidant's submission of the Prizm 2 annual report to FDA on August 19, 2003 was thus in violation of 21 U.S.C. § 333(q)(2), prohibiting the submission of any required report to FDA that is false or misleading in any material respect.

#### Facts Supporting Count Two

On or about June 21, 2004, J.R., a patient in Spain with a Renewal 1 device implanted in his chest was examined by his treating physician, during which a wireless communications link between his implanted device and a portable computer (similar to a laptop) was established through a process called "interrogation."

The interrogation of J.R.'s Renewal resulted in the computer screen displaying a bright-yellow colored warning screen which stated:

WARNING: A shorted condition on the shocking leads  
has been detected.

A LOW shocking lead impedance has been recorded.  
Please evaluate lead integrity.

Select "Reset Fault" to continue.

The screen directed the physician to "evaluate lead integrity" and did not mention the Renewal device with regard to the "shorted condition."

Having detected no problem with the leads, the physician sent J.R. home. A week later, on or about June 29, 2004, J.R. suffered a cardiac arrest at home, resulting in his death. During his cardiac arrest, J.R.'s Renewal short circuited and failed to deliver effective therapy. On or about July 5, 2004, Guidant personnel in Arden Hills, Minnesota, learned of J.R.'s death in Spain. This was the fourth Renewal arcing event of which Guidant was aware.

As Guidant personnel investigated the Renewal arcing problem in late 2004, they learned that arcing to the pulse generator prompted the warning screen to appear in all of the device malfunctions except one instance in which the arcing damage prevented the device from communicating any information.

On or about March 2, 2005, after learning of eight more Renewal arcing events, Guidant sent a "Product Update" entitled "Shorted Shock Lead Warning Screen" via commercial interstate

carrier to all physicians in the United States treating patients with Guidant CRM devices. Guidant intended the Product Update to mitigate the risk to health posed by malfunctioning Renewal devices.

The Product Update advised physicians that the yellow warning screen warned of a potentially serious problem, but did not mention any of the twelve Renewal arcing incidents of which Guidant was aware at the time of its distribution, including the death in Spain. It also did not advise that the warning screen's appearance indicated that the device may not function as intended.

Guidant's distribution of the Product Update was a medical device correction within the meaning of 21 U.S.C. § 360i and 21 C.F.R. § 806.2, which Guidant undertook to reduce a risk to health posed by the Contak Renewal 1 CRT-D.

Pursuant to 21 U.S.C. § 360i and 21 C.F.R. § 806.10, Guidant was required to submit a written report to FDA notifying it of the correction within ten working days of the correction's initiation. Guidant failed to furnish such notification as required by law in violation of 21 U.S.C. § 333(q)(1)(B).

On or about June 17, 2005, Guidant formally communicated to physicians and the public about the arcing problems with the Ventak Prizm 2 DR and Contak Renewal 1 medical devices, including information regarding the connection between the Renewal

arcing and the yellow warning screen, which was the subject of the Product Update.

AGREEMENTS AND STIPULATIONS

1. Pursuant to Rule 7(b) of the Federal Rules of Criminal Procedure, Guidant will waive indictment and plead guilty to an Information alleging the following offenses:

a. Count One of the Information will charge Guidant with violating the Federal Food, Drug, and Cosmetic Act by making materially false and misleading statements on reports required to be filed with the United States Food and Drug Administration in violation of 21 U.S.C. § 331(q)(2), a misdemeanor pursuant to 21 U.S.C. § 333(a)(1).

b. Count Two of the Information will charge Guidant with violating the Federal Food, Drug, and Cosmetic Act by failing to promptly notify the United States Food and Drug Administration of a correction it made to a medical device to reduce a risk to health posed by the device, in violation of 21 U.S.C. §§ 331(q)(1) and 360i(g), a misdemeanor pursuant to 21 U.S.C. § 333(a)(1).

2. Guidant will make a factual admission of guilt to the Court in accordance with Rule 11 of the Federal Rules of Criminal Procedure.

3. Guidant understands that by pleading guilty, it will waive its right to have any issues decided that it could have raised through pretrial motions.

4. Guidant further understands that by pleading guilty it is waiving its right to have a trial by jury and that at such

trial the Government would have to prove each element of the charged offenses beyond a reasonable doubt before Guidant could be found guilty.

5. Guidant knowingly and voluntarily waives the right to file any appeal, any collateral attack, or any other writ or motion, including but not limited to an appeal under 18 U.S.C. § 3742, that challenges the conviction, sentence, or any other matter relating to this prosecution, whether such right to appeal or collateral attack arises under 18 U.S.C. § 3742, 28 U.S.C. § 1291, 28 U.S.C. § 2255, or any other provision of law.

6. Guidant understands that the statutory maximum penalty which may be imposed against it upon conviction for each count in violation of 21 U.S.C. § 331 is a fine in an amount equal to the greatest of:

- a. \$1,000 (21 U.S.C. § 333(a)(1));
- b. \$500,000 (18 U.S.C. § 3571(c));
- c. Twice the gross pecuniary gain Guidant derived from the crime (18 U.S.C. § 3571(d)); or
- d. Twice the gross pecuniary loss caused by the crime (18 U.S.C. § 3571(d)).

7. Pursuant to Rule 11(c)(1)(C) of the Federal Rules of Criminal Procedure, the United States and Guidant agree that the appropriate disposition of this case is, and agree to recommend jointly that the Court impose a sentence requiring Guidant to pay to the United States a criminal fine of \$253,962,251 pur-

suant to 18 U.S.C. § 3571(d), payable in full not later than the later of June 30, 2010 or 10 business days after the court approves the parties' plea agreement.

8. The parties agree that while Sections 8C2.2 through 8C2.9 of the United States Sentencing Guidelines ("U.S.S.G.") do not apply to organizational defendants for misdemeanor violations of the Food, Drug and Cosmetic Act, see U.S.S.G. § 8C2.1, the agreed upon fine is consonant with those guidelines and takes into account the defendant's conduct under 18 U.S.C. §§3553 and 3572, as follows:

a. The pecuniary gain to the defendant from the offense is calculated under the sentencing guidelines to be \$144,410,693.

b. Taking into account the nature and circumstances of the offense, among other factors, and the appropriate multiplier, the resulting criminal fine is \$253,962,251.

c. This agreed-upon fine falls below the statutory maximum as set forth by 18 U.S.C. § 3571(d) (twice the gross gain or loss). The parties further agree that disgorgement is not necessary and that this fine amount will result in a reasonable sentence taking into consideration all of the factors set forth in 18 U.S.C. §§ 3553(a) and 3572.

9. As part of the disposition of this matter, Guidant agrees to a criminal forfeiture to the United States in the amount of \$42,079,675. The fine and forfeiture shall be payable not later than the later of June 30, 2010 or 10 business days after the court approves the plea agreement. The United States

will not seek additional recovery for its investigatory costs and other expenses incurred in connection with the criminal investigation and prosecution.

10. Guidant understands that the Court will order it to pay a \$250 special assessment, pursuant to 18 U.S.C. § 3013, in addition to any fine imposed.

11. The United States and Guidant jointly submit this Plea Agreement, together with the record that will be created at the plea and sentencing hearings, will provide sufficient information concerning Guidant, the crime charged in this case, and Guidant's role in the crime to enable the meaningful exercise of sentencing authority by the Court under 18 U.S.C. § 3553. Accordingly, neither the United States nor Guidant contends that a presentence investigation and report is required in this matter.

12. The United States contends that had this case gone to trial, it would have presented evidence to prove that the pecuniary gain Guidant derived from or the loss resulting from the charged offenses is sufficient to justify the recommended sentence set forth in this paragraph, pursuant to 18 U.S.C. § 3571(d). For purposes of this plea and sentencing, Guidant waives any right to contest this calculation.

13. The United States and Guidant understand that the Court retains complete discretion to accept or reject the recommended sentence provided for in this Plea Agreement.

a. If the Court does not accept the recommended sentence, the United States and Guidant agree that this Plea Agreement, except for Paragraphs 13(b) and 13(c) below, shall be rendered void.

b. If the Court does not accept the recommended sentence, Guidant will be free to withdraw its guilty plea pursuant to Fed. R. Crim. P. 11(c)(5) and (d) and to withdraw from all other provisions of this agreement.

c. In addition, Guidant agrees that, if it withdraws its guilty plea pursuant to this paragraph of the Plea Agreement, Guidant may thereafter be prosecuted for any criminal violation of which the United States has knowledge arising out of this investigation, notwithstanding the expiration of any applicable statute of limitations during the period between the date of Guidant's execution of this Plea Agreement and sixty (60) days after Guidant's withdrawal of its guilty plea. In that event, Guidant agrees that it will not raise the expiration of any statute of limitations as a defense to any such prosecution, except to the extent that the statute of limitations would have been a defense pursuant to the terms of the Tolling Agreements between the government and Guidant, and this paragraph.

14. Upon acceptance of the guilty plea called for by this Plea Agreement and the imposition of the recommended sentence, the United States agrees that it will not bring further criminal charges against Guidant LLC or any of its related corporate entities including Cardiac Pacemakers, Inc., Guidant Sales Corporation, and Boston Scientific Corporation for any act or offense committed before the date of this Plea Agreement with

regard to the issues relating to or arising from the June 17, 2005 Class I Recall of the Ventak Prizm 2 DR, Contak Renewal 1, and Contak Renewal 2 devices. The non-prosecution provisions of this paragraph are binding on the Office of the United States Attorney for the District of Minnesota, the Office of Consumer Litigation of the Civil Division of the United States Department of Justice, and the United States Attorney's Offices for each of the other judicial districts of the United States. The non-prosecution terms of this paragraph apply only to criminal matters and do not apply to any violation of the federal tax or securities laws, to any crime of violence, or to any action or prosecution by state or local authorities. Attached as Exhibit \_\_\_\_\_ to this Plea Agreement is a copy of the letter to the United States Attorney for the District of Minnesota from the Assistant Attorney General, Criminal Division, United States Department of Justice, authorizing this agreement.

15. Guidant's decision to enter into this Plea Agreement and to tender a plea of guilty is freely and voluntarily made and is not the result of force, threats, assurances, promises, or representations other than the representations contained in this Plea Agreement. The United States has made no promises or representations to Guidant as to whether the Court will accept or reject the recommendations contained within this Plea Agreement.

16. This Plea Agreement constitutes the entire agreement between the United States and Guidant concerning the disposition of the criminal charges in this case. This Plea Agreement cannot be modified except in writing, signed by the United States and Guidant.

17. Guidant will acknowledge acceptance of this Plea Agreement by the signature of its counsel and of an authorized corporate officer. Guidant shall provide to the United States for attachment as Exhibit \_\_\_\_ to this Plea Agreement a notarized resolution of Guidant's Board of Directors, authorizing the corporation to enter a plea of guilty, and authorizing a corporate officer to execute this agreement.

Dated this \_\_\_\_ day of February, 2010.


SIGNATURES FOR THE UNITED STATES OF AMERICA

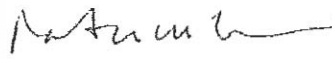
TONY WEST  
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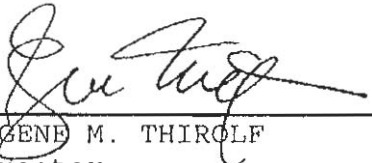
  
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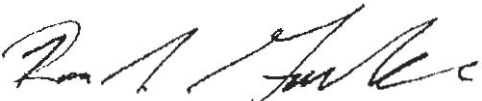
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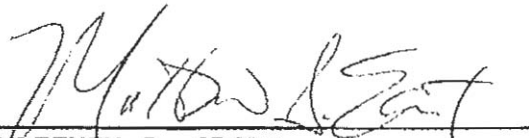
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Dated this \_\_\_\_ day of February, 2010.

SIGNATURES FOR GUIDANT LLC

GUIDANT LLC



By: TIMOTHY A. PRATT  
Vice President and  
General Counsel  
Guidant LLC

February 24, 2010

Date

JOHN M. DOWD  
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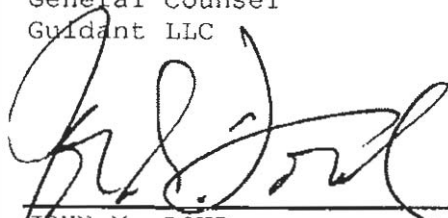
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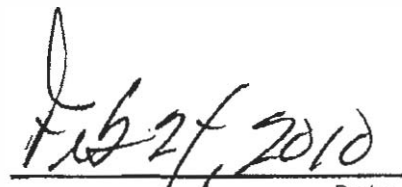
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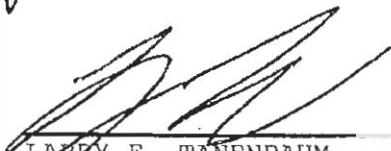
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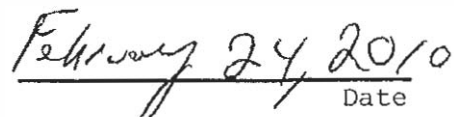
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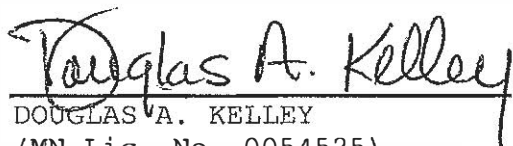
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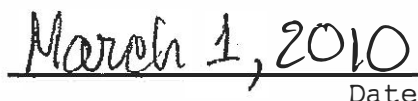
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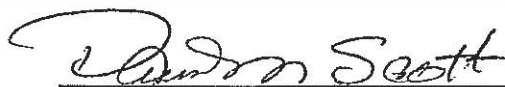
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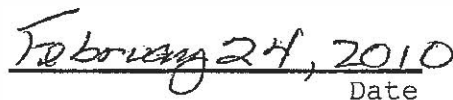
  
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